

REMARKS

Per the Examiner's request, attached hereto is a replacement page 93. This page is identical to originally submitted page 93. Also, claims 7 and 8 have been amended to depend from claim 6. The title in the application, and in the filing receipt, of "Molecules for Disease Detection and Treatment" is the correct title of the application.

Please add new claim 20. This claim is fully supported in the application as filed.

In response to the Restriction Requirement, Applicants hereby elect with traverse the claims of Group XXIII (Claims 1-5, 9-10 and 16), in part drawn to isolated polynucleotides. In response to the requirement for election of a sequence, Applicants elect with traverse to prosecute the claims related to the polynucleotide sequences of SEQ ID NO:23. Applicants reserve the right to prosecute non-elected subject matter in subsequent divisional applications.

Applicants traverse both the restriction requirement and the obligation to elect a single sequence for prosecution which were imposed in the Restriction Requirement mailed January 5, 2004 for at least the following reasons.

I. The unity of invention standard *must* be applied in national stage applications

Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides:

... [W]hen the Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111....

In applying PCT Rule 13.2 to ... national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2....

Id at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

Examiners are reminded that unity of invention (not restriction) practice is applicable ... in national stage (filed under 35 U.S.C. 371) applications.

Id at page 1800-149, column 1.

II. Specific provisions of the Administrative Regulations Under the PCT and the corresponding provisions of the MPEP strongly support a finding of unity of invention among all of the claims in the present case

1. Unity of Invention is accepted between claims to polypeptides and claims to the polynucleotides which encode them

Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT provides that unity of invention is accepted between a protein and the polynucleotide that encodes it:

Example 17

Claim 1: Protein X.

Claim 2: DNA sequence encoding protein X.

Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

Applicants submit that claims drawn to the elected polynucleotide sequence of SEQ ID NO:23 (*i.e.*, claims 1-5, 9-10 and 16 of Group XXIII) and claims drawn to a polypeptides encoded by the polynucleotides of SEQ ID NO:23 (*i.e.*, claims 13 of Group LXXIII) meet the unity of invention requirements.

Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to claims 1-5, 9-10, 13 and 16 and examine those claims in a single application.

2. Unity of invention exists among all of Applicants' claims

MPEP 1850 provides:

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims

as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Id at page 800-61.

MPEP 1893.03(d) similarly provides:

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

Id at page 1800-149.

In the present case, unity of invention exists among all of Applicants' claims. The sequences of the claimed polypeptides and the sequences of the claimed polynucleotides encoding those polypeptides are corresponding technical features which are common to all of Applicants' claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application.

3. The claimed polynucleotide sequences and the polypeptides encoded by those sequence, are corresponding technical features that are common to all of Applicants' claims and that serve to technically interrelate them

The sequences of the claimed polynucleotides and the corresponding polypeptides encoded by those polynucleotides are common to all of Applicants' claims, given that each claim refers to one or both either explicitly or implicitly, by virtue of depending from a claim which makes an explicit reference to the sequences of the claimed polynucleotides or polypeptide encoded by the claimed polynucleotides.

Moreover, the sequences of the claimed polynucleotides and corresponding polypeptides serve to technically interrelate all of Applicants' claims. Applicants' composition of matter claims 1-4, 9, 10, 13, 14 and 16 are drawn to either the polynucleotides or polypeptides themselves (claims 1-4 and 9 drawn to polynucleotides, and claim 13 drawn to polypeptides), to compositions of matter which comprise the polynucleotides as one element (claim 10 drawn to transformed cells and claim 16 drawn to a microarray), or to an antibody which specifically binds to the polypeptide (claim 14).

Therefore, the claimed polypeptide and polynucleotide sequences are corresponding technical features which are common to all of Applicants' claims, and which serve to technically interrelate them. Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application. Accordingly, withdrawal of the restriction requirement in the present case is respectfully requested.

III. Rejoinder of method claims upon allowance of product claims under U.S. practice

Applicants also submit that claims directed to methods of using the claimed polynucleotides and polypeptides encode by the claimed polynucleotides, (i.e., claims 6-8 12, 15, 17-20) could and should be examined together with the product claims from which they depend, per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products. Applicants presume these method claims will be rejoined, upon determining allowability of the product claims from which they depend.

CONCLUSION

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned. Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108**.

Respectfully submitted,
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Date: 05 February 2004

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